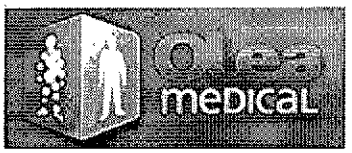


FEB 19 2009

510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number K 083491

I. Applicant Information

Applicant:

OLEA MEDICAL
6 cours Forbin
13120, Gardanne
France

Contact Person: Fayçal Djeridane
President
Tel: (011) 33 6 61 34 26 82
Fax: (011) 33 4 88 56 53 39
e-mail: faycal.djeridane@olea-medical.com

Application Correspondent:

EMERGO GROUP INC.
1705 S. Capital of Texas Hwy., Suite 500
Austin, TX 78746
U.S.A.

Contact Person: Neal Kolber
Project Manager
Tel: (512) 327-9997
Fax: (512) 327-9998
e-mail: neal@emergogroup.com

Date Prepared: October 31, 2008

II. Device Name and Classification

Proprietary Name:	NEUROSCAPE
Common/Usual Name:	PACS
Classification Name:	Picture Archiving Communications System
Regulation Number:	892.2050
Product Codes:	LLZ
Classification:	Class II
Classification Panel:	Radiology Devices

III. Predicate Device

The NEUROSCAPE device is substantially equivalent to the following FDA cleared predicate device with regard to indications for use, performance and technological characteristics:

510(k) Number:	K063539
Trade Name:	Nordic Image Control and Evaluation (nICE) Software
Manufacturer:	NordicIceMedical AS
Classification Name:	Picture Archiving Communications System
Common/Usual Name:	PACS
Regulation Number:	892.2050
Product Codes:	LLZ
Classification:	Class II

IV. Device Description

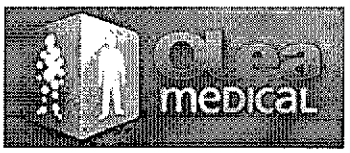
NEUROSCAPE is a medical software which helps in making informed decisions about the choice of treatment following an Ischemic Cerebral Stroke.

NEUROSCAPE enables an optimized visualization of images created by Magnetic Resonance Imaging (MRI). The device is capable of making instantaneous multi-parametric image analyses for displaying critical information such as the extent and the significance of the cerebral lesions. By providing an estimate of the lesion volume in the brain, informed decisions about whether a patient may be an appropriate candidate for thrombolytic treatment can be made.

Additionally, the display of high-definition diffusion and perfusion images and of their size change by bilinear interpolation provides the operator with an overall view of all the images, which can be efficiently and instantaneously compared. NEUROSCAPE generates a medical report, which incorporates all performed images data calculations.

The system includes the following features:

- Image Loading;
- Image Saving;
- Image Viewing;
- Image Manipulation;
- Image Analysis; and



- Image Processing.

V. Intended Use

NEUROSCAPE is a PACS image management software intended for use with general purpose computing hardware to acquire and process images and data throughout a clinical environment. Data and images are acquired through DICOM compliant imaging devices and modalities. The system is used in hospitals, imaging centers and radiologist practices by medically trained professionals.

NEUROSCAPE accepts data from existing MRI systems, allows the selection of regions of interest as defined by a trained professional and provides a measurement of the areas or volumes associated with such selected regions. These measurements are normally used by the practitioner as an aid in the assessment of ischemic cerebral stroke patients.

NEUROSCAPE is fully integrated with most existing medical image visualization applications. The system is a multi-platform software running on any Windows or Linux operating systems.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.

VI. Summary of the Technical Characteristics

NEUROSCAPE is a PACS software designed to access series of MRI perfusion and diffusion images in DICOM format. The system utilizes the information contained in each image meta-data to compare images and to perform zoom, pan and crop functions.

NEUROSCAPE displays simultaneously all the images of selected series within a particular data set in tabular format where rows represent image series and columns represent cross-sectional levels. The system allows the calculation of surfaces and volumes over a set of unfiltered images by using "segmentation masks". This also allows the user to optimize selected images by customizing the segmentation masks based on user defined areas, and to export or save the results of this image optimization into analysis reports in PDF format.

VII. Testing

OLEA Medical has conducted extensive validation testing of the NEUROSCAPE system, as a PACS system that is capable of providing reliable post-processing and display of magnetic resonance images for instantaneous multi-parametric analysis. All of the different components of the NEUROSCAPE software have been stress tested to ensure that the system as a whole provides all the capabilities necessary to operate safely and effectively.

VIII. Safety & Effectiveness Conclusions

Based on the comparison of intended use and technological characteristics, the NEUROSCAPE system is substantially equivalent to the Nordic Image Control and Evaluation (nICE) Software manufactured by NordicIceMedical AS (K063539). The NEUROSCAPE device raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 2009

OLEA Medical
c/o Mr. Ian Gordon
Senior Vice President
Emergo Group, Inc.
1705 S. Capital of Texas Highway, Suite 500
AUSTIN TX 78746

Re: K083491
Trade/Device Name: NEUROSCAPE
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 31, 2008
Received: December 2, 2008

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indication for Use Statement

510(k) Number (if known): K083491

Device Name: **NEUROSCAPE**

Indications for Use:

NEUROSCAPE is a PACS image management software intended for use with general purpose computing hardware to acquire and process images and data throughout a clinical environment. Data and images are acquired through DICOM compliant imaging devices and modalities. The system is used in hospitals, imaging centers and radiologist practices by medically trained professionals.

NEUROSCAPE accepts data from existing MRI systems, allows the selection of regions of interest as defined by a trained professional and provides a measurement of the areas or volumes associated with such selected regions. These measurements are normally used by the practitioner as an aid in the assessment of ischemic cerebral stroke patients.

NEUROSCAPE is fully integrated with most existing medical image visualization applications. The system is a multi-platform software running on any Windows or Linux operating systems.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K083491